CONCLUSION: The ICER for the maraviroc strategy is comparable to values reported for use of antiretrovirals in similar populations, and was most favorable for individuals with few active treatment options.

IN4

COST-EFFECTIVENESS OF DORIPENEM IN THE TREATMENT OF NOSOCOMIAL PNEUMONIA

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OBJECTIVE: Nosocomial pneumonia (NP), the second most common hospital-acquired infection in the US, is associated with excess morbidity, mortality, hospital days and health care costs. The objective of this study was to compare treatment costs and cost-effectiveness of doripenem (currently under FDA review for NP indication) to two common NP treatments. **METHODS:** Outcomes for a population of hospitalized patients with NP, including a subset of ventilator-associated pneumonia (VAP) patients were modeled. Patients were assumed to be treated with doripenem, imipenem or piperacillin/tazobactam as first-line therapy for NP. Clinical cure and utilization data, including receipt of concomitant medications (vancomycin/amikacin), days on mechanical ventilation (MV), ICU days, and LOS in hospital, were estimated by combining data from two randomized, multicenter, non-inferiority clinical trials of doripenem. Wholesale acquisition costs were used for study drug; costs of MV, ICU and ward days were estimated from published literature. The primary outcomes were total costs and incremental cost per clinical cure. Robustness of the baseline cost-effectiveness analysis was evaluated using one-way and probabilistic sensitivity analyses (PSA). **RESULTS:** In base-case analyses, initial treatment with doripenem was least costly at $42,041/treated patient, followed by piperacillin/tazobactam ($43,743), and imipenem ($44,834). Doripenem dominated piperacillin/tazobactam by being less costly with a higher probability of clinical cure (72.3% vs. 67.8%). Imipenem had a clinical cure rate of 72.6%, but at an additional cost of $992,200/cure. Results among the subset of VAP patients were similar. One-way sensitivity analyses show the model to be most sensitive to changes in the probability of cure with each therapy. Probabilistic sensitivity analysis results indicate that doripenem is cost saving versus imipenem in 77.1% and versus piperacillin/tazobactam in 70.6% of 1,000 iterations. **CONCLUSION:** First-line therapy with doripenem yields lower costs and similar efficacy compared to common NP treatments. Doripenem is a cost-effective treatment for NP versus imipenem and piperacillin/tazobactam.

PATIENT-REPORTED OUTCOMES RESEARCH

PR1

VARIABILITY OF HEALTH UTILITIES INDEX MARK 3 (HUI3) MEASUREMENTS DURING TREATMENT FOR ACUTE LYMPHOBLASTIC LEUKEMIA IN CHILDHOOD

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OBJECTIVE: To assess differences in serial mean utility scores, from Health Utilities Index (HUI) Mark 3 (HUI3) measurements for patients undergoing treatment for acute lymphoblastic leukemia (ALL) in childhood. These scores will be used for identifying determinants of health. **METHODS:** Patients were aged 5 years or older at time of health-related quality of life (HRQL) survey and enrolled in the Dana Farber Cancer Institute 95–001 clinical trial. Parents-of-patients completed self-administered HUI questionnaires during the four major phases of treatment: induction of remission (t1); CNS prophylaxis (t2); intensification (t3); and maintenance (t4). HRQL scores are on a scale where 0.00 equals dead and 1.00 equals perfect health. Significant differences between treatment phases, for mean HRQL and single-attribute utility scores, were assessed using 1-way ANOVA and paired t-test. Magnitude of change in mean HRQL scores between treatment phases was assessed by effect size. Differences in mean HRQL scores of >0.03 are clinically important. **RESULTS:** A total of 375 patients were surveyed (55.2% males). Patients with complete sets of parental measurements at all treatment phases were included in this analysis (n = 86). Mean HRQL score at t1 = 0.68 (SD = 0.306), t2 = 0.74 (SD = 0.245), t3 = 0.77 (SD = 0.267), and t4 = 0.88 (SD = 0.204) ($p < 0.001$). There was substantial inter-patient variability in HRQL scores within treatment phases. The effect sizes were 0.200 for t2-t1, 0.120 for t3-t2 and 0.395 for t4-t3. Mean HRQL change scores were 0.06 for t1 to t2 ($p = 0.085$), 0.03 for t2 to t3 ($p = 0.416$), and 0.10 for t3 to t4 ($p = 0.001$). For single-attribute scores significant differences between treatment phases were observed for ambulation ($p < 0.001$), emotion ($p < 0.001$), pain ($p < 0.001$). **CONCLUSION:** Mean HRQL, ambulation, emotion and pain scores generally improved over time. The large inter-patient variability may reflect, in part, the considerable heterogeneity of treatment-related side effects among patients. Further analyses will explore whether demographic or diagnostic risk factors contribute to this variability.

PR2

VALIDATION OF THE PATIENT HEALTH QUESTIONNAIRE IN BRFSS—APPLICATION OF CROSS-VALIDATION METHOD

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OBJECTIVE: Research has shown that the individuals with diabetes have a higher chance of being depressed compared to those without diabetes. To provide effective interventions for diabetes with depression, practitioners need a reliable and valid instrument to examine patients' levels of depression. The purpose of the study was to evaluate the psychometric properties of the Patient Health Questionnaire (PHQ) in 2006 Behavioral Risk Factor Surveillance System (BRFSS). **METHODS:** The BRFSS is an on-going telephone health survey system, recording U.S. adults' health and risk behaviors yearly. The PHQ measures the depressive symptom that subjects have had over the last two weeks. In the current investigation, only Washington residents who were under diabetic treatment(s) and completed the questionnaire were included in the analyses. Of 750 subjects in the analyses, 338 (45.07%) were male and 412 (54.93%) were female. The average age was 63.18 years (SD = 12.53). The split-half, cross-validation method was applied to assess the psychometric properties of the PHQ. **RESULTS:** Exploratory factor analysis was first conducted to determine the measurement structure with the first half of the sample on the first step. A one-component solution was obtained. All items loaded heavily on the target component. Cronbach coefficient Alpha was 0.82, suggesting good internal consistency. The second step involved an examination of the cross-validation of the measurement structures from first step with the second half of the sample using confirmatory factor analysis procedures. The one-factor model fitted the data well,

$\chi 2(20) = 96.73$, CFI = 0.90, GFI = 0.94, RMSEA = 0.10. The results indicated that the "felt down, depressed or hopeless" item was the most reliable indicator of the PHQ. **CONCLUSION:** Results provided the evidence of the reliability and validity of the PHQ. The measure may be useful for screening, developing and tailoring interventions to the diabetic individuals' level of depression.

PR3

IMPACT OF UNCONTROLLED PEDIATRIC ASTHMA ON HEALTH-RELATED QUALITY OF LIFE (HRQOL)

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OBJECTIVE: To assess the burden of uncontrolled asthma (UA) on HRQOL of the child and their family. **METHODS:** An internet-based survey was administered to caregivers of children aged 6–12 years with moderate to severe asthma (severity and control based on NAEPP guidelines). The caregiver questionnaire assessed pediatric asthma symptoms, rescue medication use, activity limitation, and included the Child Health Questionnaire—Parent Form 28 (CHQ-PF28), a generic instrument measuring HRQOL in children and their family. Mean CHQ-PF28 scores were calculated (ranging from 0–100, with lower scores representing greater impairment) and compared between UA and controlled asthma (CA) groups using the two-sample t-test. **RESULTS:** A total of 4,514 of 16,396 invited to participate responded. A total of 473 satisfied study inclusion criteria; 360 were caregivers of children with UA and 113 for children with CA. Seven out of 8 child-related CHQ-PF28 scale scores were significantly lower among children with UA versus CA with the greatest differences in physical functioning (mean difference = 26.8, $P < 0.0001$) and physical role limitations (mean difference = 20.0, $P < 0.0001$). Physical (mean difference = 11.7, $P < 0.0001$) and psychosocial (mean difference = 5.6, $P < 0.0001$) summary scales were both significantly lower among children with UA. Caregivers of children with UA had significantly lower scores on both parent-related scales of emotional (mean difference = 20.8, $P < 0.0001$) and time (mean difference = 16.3, $P < 0.0001$) impact, and 1 of 2 family-related scales (activities, mean difference = 19.3, $P < 0.0001$). **CONCLUSION:** Uncontrolled asthma was associated with significant impairment in HRQOL, extending beyond the physical health of the child to their psychosocial development. Additionally, uncontrolled pediatric asthma had a significant HRQOL impact on the caregiver and family.

PR4

EVALUATION OF IMPACT OF ORAL TOPOTECAN ON HEALTH-RELATED QUALITY OF LIFE IN RELAPSED SMALL CELL LUNG CANCER

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OBJECTIVE: Relapsed small cell lung cancer (SCLC) carries a poor prognosis and is associated with poor health-related quality of life (HRQoL). This study assesses the impact of oral topotecan (OT) on HRQoL when used as second-line treatment for relapsed SCLC. **METHODS:** Data from a randomized, open-label, multicenter clinical trial were analyzed, including 141 patients with relapsed SCLC receiving either OT plus best supportive care (BSC) or BSC alone. EQ-5D, a widely used measure of HRQoL that produces both a visual analogue scale (VAS) and an index-based utility score, was administered at baseline and subsequently at three-week intervals. Changes in HRQoL from baseline were compared between two groups by measuring 1) changes between baseline and last evaluation, and 2) changes between baseline and all on-treatment evaluations (pooled analysis). Published criteria for interpretation of minimally important differences (MID) in cancer, i.e., UK-based utility score changes of 0.10 or more and VAS score changes of 8 or more, were used to further interpret results (Pickard AS, et al. *HQLO*, 2007). **RESULTS:** Patients receiving OT + BSC experienced better HRQoL outcomes compared to patients receiving BSC alone. Mean declines from baseline to the last evaluation were significantly smaller in the OT + BSC than BSC alone group in EQ-5D utility (–0.10 vs. –0.30, $p = 0.0078$) and VAS (–3.98 vs. –14.46, $p = 0.0044$) scores. Similarly, in the pooled analysis, the OT + BSC group exhibited significantly smaller declines from baseline than the BSC alone group in both EQ-5D utility (–0.04 vs. –0.18, $p = 0.0045$) and VAS (–0.71 vs. –8.83, $p = 0.0035$) scores. Using previously established criteria for MIDs, the differences in HRQoL decline between two groups were statistically significant and clinically meaningful. **CONCLUSION:** Patients receiving OT + BSC experienced smaller declines in HRQoL from baseline than patients receiving BSC alone. Differences in change from baseline between groups exceeded MIDs from previous studies, indicating a meaningful clinical benefit.

WOMEN'S HEALTH OUTCOMES RESEARCH

WH1

EXPOSURE TO CONTRAINDICATED AND OTHER POTENTIALLY DANGEROUS MEDICATIONS DURING PREGNANCY: A POPULATION BASED STUDY IN ITALY

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OBJECTIVE: To estimate the burden of exposure to medications associated with known or suspected risk of fetal harm among pregnant women in Regione Emilia-Romagna (RER), Italy. **METHODS:** A prevalence study was conducted using the RER health care database, including data for the entire RER population of about 4 million inhabitants. Female residents of RER who delivered a baby in a hospital between January 1, 2004 and December 31, 2004 were identified via ICD-9-CM codes. All prescription drug data were reviewed for the 270 days leading up to date of delivery. Drugs were grouped into pregnancy risk categories (A, B, C, D, X) using established classification systems. Contraindicated drugs were defined as category X drugs and potentially dangerous drugs were defined as category D drugs. Women exposed to contraindicated and potentially dangerous drugs in the 270 days prior to delivery were identified. **RESULTS:** Among the 33,343 deliveries identified in 2004, 70% were exposed to at least one prescription medication in the 270 days prior to delivery. Approximately 1% of women were exposed to drugs contraindicated in pregnancy (category X), including 189 women (0.6%) receiving these drugs during the first trimester. Approximately 1.5% of women were exposed to potentially dangerous (category D) drugs. Measurable proportions of women were exposed to ACE-inhibitors (0.79%) and HMG-CoA reductase inhibitors (0.28%), which have recently been linked to risk of fetal malformations. **CONCLUSIONS:** For the entire RER population,